

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM
OFFICIAL OR OWN STANDARDS**

2918. Adulteration and misbranding of chorionic gonadotropic hormone. U. S. v. 54 Cartons, etc. (F. D. C. No. 27279. Sample Nos. 11292-K, 11293-K.)

LIBEL FILED: June 6, 1949, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 14 and February 20, 1948, from Philadelphia, Pa.

PRODUCT: 54 cartons and 75 cartons, each carton containing 1 unlabeled vial, of *chorionic gonadotropic hormone* at Richmond Hill, N. Y. Each lot was accompanied by sticker labels on the shipping cartons which represented that the 54-carton lot contained 500 International Units of *chorionic gonadotropic hormone* per vial and that the 75-carton lot contained 1,000 International Units of *chorionic gonadotropic hormone* per vial. The vials and the 1-vial cartons were labeled after shipment in interstate commerce.

Analyses showed that the product (both lots) contained less than half of the declared amounts of *chorionic gonadotropic hormone*.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to the article, which contained less than half of the declared amounts of *chorionic gonadotropic hormone*: (54-carton lot) "Each 1 cc will contain 500 international units of chorionic gonadotropic hormone when 10 cc of triple distilled water is added to this vial" and (75-carton lot) "Each 1 cc will contain 100 international units of chorionic gonadotropic hormone when 10 cc of triple distilled water is added to this vial."

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 9, 1949. Default decree of condemnation and destruction.

2919. Adulteration and misbranding of surgical dressings. U. S. v. 126 Packages, etc. (F. D. C. No. 28341. Sample Nos. 33682-K, 33683-K.)

LIBEL FILED: November 22, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about October 4, 1949, by Surgical Dressings, Inc., from Boston, Mass.

PRODUCT: 126 packages, each containing 1 roll, of bandage 1½" x 12" and 114 packages, each containing 1 roll, of bandage 2" x 24" at Sacramento, Calif. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "Sterilastic Dressing Bandage."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements appearing on the package labels of the article were false and misleading as applied to an article which was not sterile: (1½" x 12" size) "Sterilastic * * * First Aid Wound Protection * * * Both the Sterilastic and the Gauze in this Package have been sterilized * * * Surgical Dressing" and (2" x 24" size) "Sterilastic First Aid Bandage * * * Surgical Dressing * * * The gauze supplied with Sterilastic may be used in an emergency."

DISPOSITION: December 8, 1949. Default decree of condemnation and destruction.